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APPLICATION NO.	FILING OR 371(C) DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,488	12/10/2003	Yaron Ilan	59046.000044	7675

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,488	ILAN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/04/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-52 and 55-62* is/are pending in the application.

4a) Of the above claim(s) *61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-52, 55-60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/04/2009 has been entered.

Status of Claims

2. Claims 1-49 and 53-54 are cancelled. Claims 50-52 and 55-62 are pending. Claim 61 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/02/2005. Claims 50-52, 55-60 and 62 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim recites "beta-glucosylceramide and a beta-galactosylceramide". To support the addition of the noted recitation, Applicant cited page 13, line 23-page 14, line 18 of the specification. The Office has thoroughly reviewed the cited passages, along with the complete disclosure. Support of the noted recitation cannot be found at the cited passages or within the entire disclosure. Therefore, the rejection of the claim for failing to comply with the written description requirement is appropriate.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 50-52 and 55-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Motoki et al.[1]

The claims are directed to a process comprising the administration of a glycolipid to a diseased subject. Claim 51, which depends on claim 50, requires the administration to modulate the cellular, humoral or cytokine elements of the immune system of the subject. Claim 52, requires the modulation to be specific or non-specific. Claim 55, which depends on claim 50, requires the glycolipid to comprise a

[1] Motoki et al. Immunostimulatory and antitumor activities of monoglycosylceramides having various sugar moieties. Biol. Pharm. Bull., November 1995, Vol. 18, No. 11, 1487-1491.

monosaccharide ceramide. Claim 56, which depends on claim 55, requires that the monosaccharide ceramide to be beta-glucosylceramide or beta-galactosylceramide. Claim 57, which depends on claim 50, requires the administration be intravenous, intramuscular, subcutaneous, intraperitoneal or oral. Claim 58, which depends on claim 50, requires the subject to have cancer.

Motoki et al. teaches a process comprising the administration of a glycolipid to a diseased subject. The glycolipid administered, subcutaneously, by Motoki et al. are beta-glucosylceramide or beta-galactosylceramide, monosaccharide ceramide. The subject of Motoki et al. has cancer. Motoki et al. also demonstrates that the glycolipid is immunostimulatory. In the instant case, Motoki et al. teaches the claimed invention. Motoki et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 50, 58-60 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki et al., as applied to claims 50 and 58, in view of Ogawa et al.[2]

Claim 59, which depends on claim 58, requires the infection to be viral or bacterial. Claim 60, which depends on claim 59, requires the viral infection to be HBV, HCV, or HIV.

The significance of Motoki et al., as applied to claims 50 and 58, is provided above. The subject of Motoki et al. is not a virally infected subject, including humans. However, at the time the invention was made, Ogawa et al. also teaches that glycolipids, including beta anomers of the glucosylceramide and galactosylceramides closely relates to receptor functions for physiologically active substances and important cell functions, such as generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions. Ogawa et al. also establishes that it is known that glycolipids play a role as a receptor in the host side in the infection with bacteria and viruses. [Lines 55-61, column 1, in particular.]Based on this knowledge, Ogawa et al. discloses the use of glycolipids to inhibit viral infections. Thus, at the time the invention was made, Ogawa et al. establishes that glycolipids have antiviral activities.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer the glycolipids taught by Motoki et al. to a virally infected subject, including human and those infected with HBV, HCV or HIV. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to inhibit viral infection or to induce an immune response against the infection. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the antiviral activities of glycolipids has been demonstrated and established by Ogawa et al.

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[2] Ogawa et al. U.S. Patent No. 5861520, published January 19, 1999.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. In response to the provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting, Applicant requested that the rejection be held in abeyance until the finding of allowable subject matter.

Applicant's request has been noted, however, until the rejection is properly addressed, it is maintained on the record.

11. Claims 50-52, 55-60 and 62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 9 and 11 of copending Application No. 10/375906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are directed at a process comprising the administration of a glycolipid to a virally infected subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
Primary Examiner, Art Unit 1648